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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,534	03/12/2004	Long Sheng Yu	25658-455002	7819

7590
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01/29/2007

EXAMINER

ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/799,534

Applicant(s)

YU ET AL.

Examiner

Alyssa M. Alter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 3 and 12-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "attached" to --adapted to be attached --.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 2-7 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 2-7, since claim 1 recites an assist device, claims 2-7 should recite a preamble of --a ventricular assist device of claim 1, wherein said adapter sleeve--.

As to claims 3 and 12, the "sewing ting" is merely inferentially included and it is unclear if the ring is being positively recited or merely a functional recitation.

As to claim 5, it is unclear if the recitation of a "sleeve may be separated", means the sleeve is separated or is not separated.

As to claim 12, it is unclear if the recited of "length including" refers to the sleeve or the sleeve and inflow tube combination.

Claim Rejections - 35 USC § 102

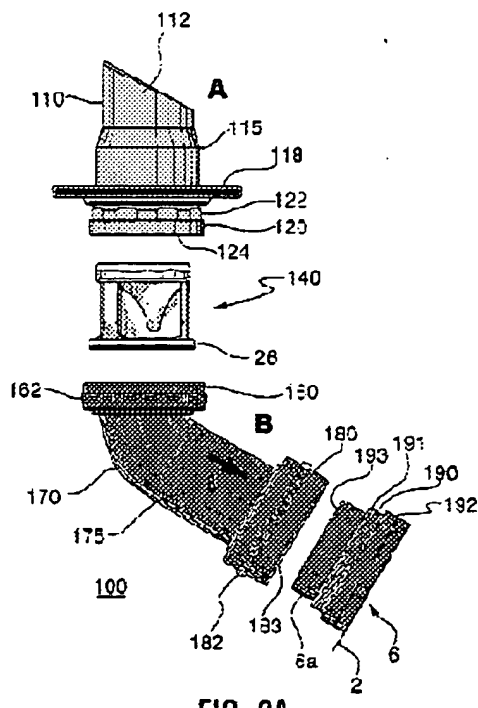
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-5 and 7-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Mussivand et al. (US 6,290,639). Mussivand et al. discloses a conduit assembly in figure 1 and 2A. As seen in figure 1, the system includes a VAD 2 as a pump portion, an inflow tube protruding from the pump and an adapter sleeve. The inflow tube and

adapter sleeve can be seen more clearly in the replication of figure 2A below.



In figure 2A, the inflow tube is depicted as portion B and the adapter is depicted as portion A, as indicated accordingly.

As to claims 9, 11 and 13, since the inflow tube also includes the inflow port extension 6a, the examiner considers the inflow tube to be

extendable. Furthermore, this inflow port extension 6a is also an inner sleeve that extends inside the inflow tube.

As to claims 2-3 and 7, the adapter also includes a sewing ring or skirt 118 to suture to the ventricular apex. Furthermore, the examiner also considers the sewing ring or skirt 118 to be a gripping member for attaching the inflow tube to the ventricular apex.

As to claim 4, for the "material of rigid components, it is preferable to use titanium"(col.7, lines 56-57) and as seen in the figures. The sleeve is smooth.

As to claim 5, the examiner considers the threads of the "threaded connection 120" (col.6, lines 50-51) within the adapter sleeve to be the grooves where the sleeve can be separated.

As to claim 8, the elbow assembly 170 is the bent end of the inflow tube as seen in figure 2A.

As to claim 10, "The gland nut 180 provides a rotatable union effect during the fitting procedure. That is, the gland nut 180 moves between a rotatable position and a locked position. At the rotatable position, the gland nut 180 allows the inflow elbow conduit 175 to rotate about its axis into any rotated position relative to the VAD 2, when the VAD 2 is implanted"(col. 4, lines 43-48). Therefore the end of the inflow tube is rotatable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussivand et al. (US 6,290,639). Mussivand et al. discloses the claimed invention but does not disclose expressly the ceramic material. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the adapter sleeve as taught by Mussivand et al., with the ceramic adapter sleeve, because Applicant has not disclosed the ceramic material provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the titanium adapter

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sleeve as taught by Mussivand et al., because both materials are biocompatibility and frequently incorporated in implantable devices.

Therefore, it would have been an obvious matter of design choice to modify the material for titanium to ceramic to obtain the invention as specified in the claim(s).

Furthermore, Mussivand et al., discloses the claimed invention except for the ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material to ceramic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416 (See MPEP 2144.07)

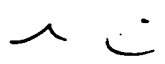
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762


GEORGE R. EVANISKO
PRIMARY EXAMINER

1/22/7